REGULATORY CONSIDERATIONS FOR NANOTECHNOLOGY IN PUBLIC HEALTH

FOOD AND DRUG ADMINISTRATION
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FDA REGULATES

- 20 percent of the consumer purchases
- $50 billion of medical R&D
- 8 million import shipments/year
- Food, drugs, biologicals, devices, cosmetics, blood
- Counter terrorism products

FDA REGULATED PRODUCTS

- Foods
  - All interstate domestic and imported, including produce, fish, shellfish, shell eggs, milk (not meat or poultry)
  - Bottled water
  - Wine (<7 alcohol)
  - Infant formula
- Food additives
  - Colors
  - Food containers
- Cosmetics
- Dietary Supplements
- Animal Feeds
- Pharmaceuticals
  - Human
  - Animal
  - Tamper resistant packaging
- Medical devices
- Radiation emitting electronic products
- Vaccines
- Blood products
- Tissues
- Sterilants
- Counter-terrorism products

FDA ORGANIZATION

- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research
- Center for Devices and Radiological Health
- Center for Food Safety and Applied Nutrition
- Center for Veterinary Medicine
- Office of Regional Operations
- National Center for Toxicological Research

NANOTECHNOLOGY DEFINTION

- The existence of materials or products at the atomic, molecular, or macromolecular levels, where at least one dimension that affects the functional behavior of the drug/device product is in the length scale of approximately 1-100 nm range.
- The creation and use of structures, devices and systems that have novel properties and functions because of their small and/or intermediate size.
- The ability to control or manipulate on the atomic scale.

RISK MANAGEMENT APPROACH

- FDA regulates products on a product-by-product basis
  - Pre-market approval
  - Pre-market “acceptance”
  - Post-market
- FDA does not regulate “technologies”
- Product review process is not static – as we learn more, we evolve the process
- Provide assistance to the industry we regulate

FDA CONSIDERATIONS FOR NANOSIZED PRODUCTS

- Nomenclature
- Quality
- Safety
- Environmental
- Many approved products of nano-sized components
- Drugs and devices are in nano-size range at site of action

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"NANOSIZING" OF DRUGS

- Particle size reductions of drugs has the potential to:
  - Increase surface area
  - Enhance solubility
  - Increase rate of dissolution
  - Increase oral bioavailability
  - More rapid onset of therapeutic action
  - Decrease the dose needed
  - Decrease fed/fasted variability
  - Decrease patient to patient variability

FDA NANOTECHNOLOGY FAQS

- Who will review nanotechnology products?
- What will be the requirements for nanotechnology products?
- Does FDA have a nanotechnology research program?

WHO WILL REVIEW?

- Product specific – specific product center
- Many expected to be combination product – Office of Combination products
  - Specific center designated primary responsibility
  - Consultations with other centers

WHAT WILL BE THE REQUIREMENTS FOR APPROVAL?

- Products are reviewed on product by product basis
- FDA has in place guidance/requirements for most products
- To date there have been no issues with current products as a result of size
- Concern for unidentified issues – Will address those as they develop

DOES FDA HAVE A NANOTECHNOLOGY RESEARCH PROGRAM?

- Skin absorption and phototoxicity of titanium dioxide and zinc oxide and dermal penetration of quantum dots.
- In vitro assays to assess toxicity of nanoparticles
- Characterization of physical and chemical properties of nanoparticles

FDA NANOTECHNOLOGY POLICY COORDINATION

- FDA is a member of the Nanoscale Science and Engineering Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC) Committee on Technology
- FDA co-chairs the NSET Nanomaterials Environmental and Health Implications (NEHI) Working Group
- Within FDA, Nanotechnology Interest Group meets quarterly to review nanotechnology issues across the product centers.
- FDA product centers have regular discussion group meetings to review issues within their respective centers.
- FDA nanotechnology research programs

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NANO-REGULATORY ISSUES

- FDA has only limited authority for potentially high risk nano-products (e.g., cosmetics)
- Existing pharmtox tests are probably adequate for most nano-products
- Nomenclature – What is a nano-particle? What are properties of nano-particles? Same chemical – smaller size – new formal definition?
- Limited basic public health research on nano-materials
- For new nano-materials, new “tools” may be needed

CHALLENGES!!

- New technology - unknown risks
- Education - A bad job here can minimize the utility
- Stakeholder involvement
  - Early involvement of all parties
  - Risk communication
- Communication with new manufacturers
- Timely reporting of relevant scientific findings

APPROVAL WHEN?

- Open communication between nanotechnology/medical product manufacturers and FDA
- Ask for FDA assistance
- FDA web site: www.fda.gov/nanotechnology
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